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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,854	11/21/2001	Phong D. Doan	A01P1084	4896

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PACESETTER, INC.
15900 Valley View Court
Sylmar, CA 91392-9221

EXAMINER

DROESCH, KRISTEN L

ART UNIT PAPER NUMBER

3762

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,854

Applicant(s)

DOAN ET AL.

Examiner

Kristen L Drosch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9 and 12-22 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is inaccurate because the spiral track member (122) does not engage the helix (102), rather it engages the follower member (140) of the electrode. The helix is prevented from even entering the spiral track member due to the existence of member 138.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 7, 12-17, and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Soukup (5,020,545).

Regarding claims 1-2, 7, 16-17, and 19, Soukup shows an electrically active housing or electrode (52, 54) comprising a tubular end region extending to a terminal rim at the distal end; an electrical conductor (38, 40); an active fixation electrode (50, 80) comprising a helix (82); and a guide system comprising a spiral track member (182, 183) located proximally of the active fixation electrode adapted to engage the active fixation electrode (50, 80) (Figs. 1-4, 6-7).

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With respect to claim 3, Soukup shows the electrically active housing (52, 54) further comprises a generally planar bulkhead member (66); a tubular end region (72); the spiral track member (182, 183) of the guide system extends proximally away from the bulkhead member (66) to a proximal rim (Fig. 7); and the active fixation electrode comprises a conductive shaft (50, 80) having an outer peripheral surface and having an outwardly projecting follower member (94, 95) slidably engaged with the spiral track member (Col. 8, lines 42-55; Fig. 7). For further clarification, the examiner considers the inward portions (facing the proximal end of the lead) of projections (66) at the terminal end of the lead to be the bulkhead, and the outer portion of the projections (66) that would be in contact with tissue to be the terminal rim, and the surface of the opening (72) to be the tubular end region extending away from the bulkhead member to the terminal rim at the distal end of the lead.

With respect to claims 4 and 22, Soukup shows an insulation sheath covering the electrical conductor, and an electrical connector (16, 18) coupled to the proximal end of the conductor (38, 40) (Col. 5, lines 3-14).

Regarding claim 12, Soukup further shows the electrically active housing comprises an electrically active collar (52) coaxial with the helix at the distal end of the lead (Fig. 1).

With respect to claim 13, Soukup further shows the electrically active helix (82) is fixed to a distal end of the conductive shaft (Fig. 1).

Regarding claims 14-15, Soukup further shows a the guide system comprises a cylindrical guide member integral with and extending proximally away from the bulkhead member (66) of the electrically active housing (52, 54) and comprising a spiral track member

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(182, 183) and defined by opposed spaced parallel side walls and a bottom wall connecting the side walls (Fig. 7).

With respect to claim 20, Soukup further shows the endocardial lead comprises a conductive shaft (50, 80) coupled between the distal end of the electrical conductor and the helix, and the conductive shaft (50, 80) having an outer peripheral surface and having an outwardly projecting follower member (94, 95) slidably engaged with the spiral track member (Col. 8, lines 42-55; Fig. 7).

Regarding claim 21, Soukup shows the guide system comprises a cylindrical guide member having an inner peripheral surface, wherein the spiral track member (182, 183) of the guide system is formed into the inner facing peripheral surface of the cylindrical guide member and defined by opposed spaced parallel side walls (Fig. 7).

5. Claims 1-2, 4-5, 7, 12, 16, 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Grassi (4,624,265).

Regarding claims 1-2, 7, 16-17, and 19, Grassi shows an electrically active housing or electrode (5, 21) comprising a tubular end region extending to a terminal rim at the distal end; an electrical conductor (2); an active fixation electrode comprising a helix (15); and a guide system located proximally of the active fixation electrode (helical portion 15 of active electrode) comprising a spiral track member (20) adapted to engage the active fixation electrode (15) (the proximal threaded portion) (Figs. 1, 4).

With respect to claims 4 and 22, Grassi shows an insulation sheath (1, 6) covering the electrical conductor. It is inherent that there is an electrical connector coupled to the proximal end of the conductor in order to connect the lead to a ICD/pacemaker.

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Regarding claim 5, Grassi shows that a resilient coupling mechanism (14, 16) for maintaining electrical continuity between the active fixation electrode (15) and the electrically active housing (5, 21).

With respect to claim 12, Grassi further shows the electrically active housing comprises an electrically active collar (21) coaxial with the helix at the distal end of the lead (Fig. 4).

With respect to claim 20, Grassi further shows the endocardial lead comprises a conductive shaft (14) coupled between the distal end of the electrical conductor and the helix, and the conductive shaft (14) having an outer peripheral surface and having an outwardly projecting follower member slidably engaged with the spiral track member (20) (Fig. 4).

Regarding claim 21, Grassi shows the guide system comprises a cylindrical guide member having an inner peripheral surface, wherein the spiral track member (20) of the guide system is formed into the inner facing peripheral surface of the cylindrical guide member and defined by opposed spaced parallel side walls (Fig. 4).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8-9, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soukup (5,020,545) as applied to claims 2, and 16, and further in view of Vachon et al. (5,447,533). Soukup is as explained before. Although Soukup fails to teach a therapeutic

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element integral with the active fixation electrode, generally cylindrical in shape and coaxial with and fixed on the distal end of the conductor and formed of a matrix material of sufficient rigidity to penetrate myocardial tissue, attention is directed to Vachon et al. which shows a lead with a therapeutic element (62) having these characteristics. Vachon teaches that it is highly desirable to have an a therapeutic element that is capable of penetrating the myocardial wall because therapeutic material eluted from the surface of the electrodes of prior art leads would be washed away by blood pumping through the heart (Col. 2, line 39- Col. 3, line17). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the lead of Soukup to include a therapeutic element integral with the active fixation electrode, generally cylindrical in shape and coaxial with and fixed on the distal end of the conductor and formed of a matrix material of sufficient rigidity to penetrate myocardial tissue as Vachon et al. teaches in order to avoid the therapeutic material from being washed away by blood pumping through the heart.

8. Claims 8-9, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (4,624,265) as applied to claims 2, and 16, and further in view of Vachon et al. (5,447,533). Grassi is as explained before. Although Grassi fails to teach a therapeutic element integral with the active fixation electrode, generally cylindrical in shape and coaxial with and fixed on the distal end of the conductor and formed of a matrix material of sufficient rigidity to penetrate myocardial tissue, attention is directed to Vachon et al. which shows a lead with a therapeutic element (62) having these characteristics. Vachon teaches that it is highly desirable to have an a therapeutic element that is capable of penetrating the myocardial wall because therapeutic material eluted from the surface of the electrodes of prior art leads would be washed away by

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blood pumping through the heart (Col. 2, line 39- Col. 3, line 17). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the lead of Grassi to include a therapeutic element integral with the active fixation electrode, generally cylindrical in shape and coaxial with and fixed on the distal end of the conductor and formed of a matrix material of sufficient rigidity to penetrate myocardial tissue as Vachon et al. teaches in order to avoid the therapeutic material from being washed away by blood pumping through the heart.

Response to Arguments

9. Applicant's arguments with respect to claims 1-2, 4-5, 7, and 12 have been considered but are moot in view of the new ground(s) of rejection.

10. Applicant's arguments filed 3/30/04 have been fully considered but they are not persuasive.

In response to applicant's arguments that Soukup does not disclose or suggest a guide system having a spiral track member adapted to engage an active fixation electrode for rotating the electrically active helix about the longitudinal axis as the helix is moved between the retracted and extended positions, the examiner respectfully disagrees. In Figure 7, and Col. 8, lines 42-55, Soukup shows a spiral track member (182, 183) adapted to engage an active fixation electrode (50, 80).

Allowable Subject Matter

11. Claim 6 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim (2) and any intervening claims (3).

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The prior art of record fails to teach or suggest a lead with an active fixation electrode having a conductive shaft with a outwardly projecting follower member slidably engaged with a spiral track member of an electrically conductive housing, an annular collar integral with the conductive shaft projecting radially from the longitudinal axis to an outer rim beyond the outer surface of the conductive shaft, a head portion coaxial with and extending distally from the annular collar and having a diameter smaller than the annular collar defining a distal annular shoulder; and a compression spring engaged between a planar bulkhead member of the conductive housing and the distal annular shoulder, where the annular collar and distal annular shoulder are located proximal from the bulkhead member.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185.

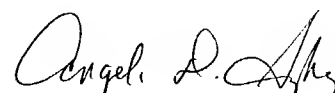
The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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